

### **REMARKS**

#### **Status of the Application**

Applicants note that the outstanding Office Action is indicated as final. However, the Examiner in a telephone call to the undersigned indicated that the outstanding Office Action is in fact a non-final Office Action. See Interview Summary dated January 30, 2007.

Claims 1, 4-8, and 10-18 are currently pending in the application. Claims 1, 4-8, and 10-18 stand rejected. Claims 17 and 18 are currently amended. Claims 2, 9, 19 and 20 are canceled. Reconsideration and allowance of all of the pending claims is respectfully requested.

New matter is not being introduced into the application by way of this amendment. Claim 17 is currently amended to incorporate the subject matter of claim 19, and claim 18 is currently amended to incorporate the subject matter of claim 20. Accordingly, no new matter is added and entry of this amendment is respectfully requested.

#### **Claim Rejections - 35 U.S.C. §112**

Claim 8 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the use of a non-porous acetyl cellulose film is not enabled by the specification. Applicants respectfully traverse this rejection for the following reasons.

Applicants respectfully submit that the MPEP is clear on what is required for an Examiner to make and maintain an enablement rejection under 35 U.S.C. §112:

In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken

as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

MPEP §2164.04 (citations omitted).

Applicants note that the specification clearly describes that non-porous acetyl cellulose will work with the present invention, and in fact is a preferred embodiment. See specification at page 3, lines 6-7. However, the Examiner contends that the specification does not provide working examples of non-porous membranes, and further contends that the state of the art suggests that only porous acetyl cellulose films can be used with the present invention. See Office Action, pages 2-3, bridge paragraph. However applicants respectfully submit that there is no teaching or suggestion in the prior art that indicates that only porous acetyl cellulose films can be used with the present invention.

Mullis indicates that porous membranes are generally used with their methods, however Mullis does not suggest that only porous membranes can be used with methods of adsorbing and desorbing nucleic acid as presently claimed. The present methods will work on either a porous or non-porous membrane that has been surface saponified as presently claimed. In fact, as mentioned, the present specification expressly states that non-porous acetyl cellulose is a preferred embodiment at page 3, lines 6-7. Applicants respectfully submit that the Examiner has offered no reason to doubt that Applicant's disclosure is objectively correct in stating that surface saponified, non-porous membranes will work in the presently claimed methods. Accordingly, withdrawal of this rejection is required.

**Claim Rejections - 35 U.S.C. §103**

Claims 1, 2, 7, 9, 12, and 14-16 are rejected as unpatentable over Mullis (U.S. Patent No. 5,187,083) in view of a printout of the GE Osmonics labstore website showing commercially available GE CA (Cellulose Acetate) Membranes, and further in view of Bryk et al. (*Porous structure of cellulose acetate ultrafiltration membranes of various degrees of saponification*, Polymer Science USSR, vol. 32, issue 7, (1990) pp. 1401-1409). Applicants respectfully traverse this rejection for the following reasons.

As an initial matter, Applicants respectfully note that the printout of the GE Osmonics labstore website does not indicate a date. Accordingly, applicants do not concede that Osmonics labstore website printout represents prior art to the present application.

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP §2143.03. Applicants respectfully submit that all of the limitations of claim 1 are not taught or suggested by the prior art. The prior art does not disclose or suggest using a surface saponified cellulose acetate membrane to adsorb and desorb nucleic acid to and from a membrane as recited in claim 1. Accordingly, all of the limitations of the present claims are not disclosed or suggested by the prior art, and this rejection must be withdrawn.

The Examiner mentions in the Office Action that Mullis discloses using cellulose acetate membranes to separate nucleic acid, but Mullis does not disclose the use of surface saponified cellulose acetate membranes. See Office Action, page 6, first full paragraph. However, the Examiner cites Bryk as disclosing surface saponified cellulose acetate membranes, and asserts

that it would be obvious to use the surface saponified membranes of Bryk in the methods of Mullis.

Bryk in fact discloses a study of surface saponified cellulose acetate membranes, and discloses the effects of saponification on the underlying structure of the membranes. See Bryk, Abstract. However, Bryk does not mention separating and purifying nucleic acid as presently recited in claim 1. Accordingly, Mullis in view of Bryk does not disclose or suggest adsorbing and desorbing nucleic acid on surface saponified membranes as presently claimed. Therefore all of the claim limitations are not expressly disclosed or suggested by the prior art and this rejection must be withdrawn.

In addition, the prior art does not provide a suggestion for combining the asserted references. Applicants submit that Bryk suggests that saponified cellulose acetate membranes are less effective as ultrafiltration membranes due to the increase in the rigidity of the polymer chains, and the corresponding decrease in the ability of the material to mix with a solvent that was observed in the study. See page 1408, fifth full paragraph. Accordingly, Bryk does not offer a suggestion for using saponified cellulose acetate membranes for adsorbing and desorbing nucleic acid on surface saponified cellulose acetate membranes as presently claimed. Applicants respectfully submit that this rejection must therefore be withdrawn.

## *2. Mullis in view of GE Osmonics and Tucelli*

Claims 1, 2, 9, and 10 are rejected under 35 U.S.C. §103(a) over Mullis as evidenced by the GE Osmonics web page in view of Tucelli (U.S. Patent No 5,522,991). Applicants respectfully traverse this rejection for the following reasons.

Tucelli is also cited in the Office Action as disclosing saponified cellulose acetate membranes. However, Tucelli only mentions the processing of protein containing solutions with their membranes. See col. 2, lines 24-25. Accordingly, Mullis as evidenced by the GE Osmonics web page in view of Tucelli does not disclose or suggest adsorbing and desorbing nucleic acid with surface saponified cellulose acetate membranes as recited in claim 1. Accordingly, all of the limitations of the present claims are not disclosed or suggested by the prior art and this rejection must be withdrawn.

In addition, applicants respectfully submit that there is no motivation or suggestion in the prior art to combine the asserted references. Applicants submit that it is well known in the art that proteins have entirely different chemical properties from nucleic acid. One of skill in the art would not expect surfaces typically used with DNA to be generally adaptable to the separation of proteins. This is due to the well known biochemical differences between the two classes of biomolecules. Accordingly, one of skill in the art would have no motivation or suggestion to combine Mullis as evidenced by the GE Osmonics web page with Tucelli. Applicants submit that this rejection must be withdrawn.

*3. Mullis in view of the GE Osmonics web page and Kuroita or Heath*

Claims 10 and 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mullis as evidenced by the GE Osmonics web page, in view of Bryk et al. and further in view of Kuroita (U.S. Patent No. 5,990,302). Claims 17 and 18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mullis as evidenced by the GE Osmonics web page in further view of Heath (WO 99/13976). Applicants respectfully traverse each of these rejections for the following reasons.

The Examiner applies Mullis and the GE Osmonics web page as discussed above as primary references, and further cites Kuroita for the disclosure of the features recited in dependent claims 10 and 11. The Examiner also applies Mullis and the GE Osmonics web page as discussed above as primary references, and further cites Heath for the disclosure of the features recited in dependent claims 17 and 18.

However, applicants respectfully submit that Mullis and the GE Osmonics web page do not disclose or suggest all of the elements of claim 1 as discussed above. Accordingly, Mullis and the GE Osmonics web page do not disclose or suggest all of the elements of claims 10 and 11 which depend from claim 1. Withdrawal of this rejection is therefore required.

Applicants also submit that method claims 17 and 18 incorporate all of the limitations of claim 1. Therefore since claim 1 is demonstrated above as being patentable over the prior art, dependent claims 17 and 18 are also patentable over the prior art. Accordingly, withdrawal of this rejection is required.

#### *4. Claims 19 and 20*

Claims 19 and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mullis as evidenced by the GE Osmonics web page and further in view of Bryk. Claims 19 and 20 are also rejected under 35 U.S.C. §103(a) as being unpatentable over Mullis as evidenced by the GE Osmonics web page, and further in view of Heath and Tucelli. Applicants respectfully traverse each of these rejections for the following reasons.

Claims 19 and 20 are canceled by this amendment rendering these rejections moot. Accordingly, withdrawal is respectfully requested.

### **Double Patenting Rejections**

Claims 1, 4-8, and 10-18 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 1-2 of copending application 10/305,110 and claims 1-18 of copending application number 10/621,412; and claims 1-20 of copending application number 10/621,715 in view of Tam (U.S. Patent No. 5,741,647). This rejection is respectfully traversed.

The applicants respectfully refer the Examiner to the MPEP §804, page 800-17, the relevant section of which is provided below:

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

### **Conclusion**

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a one (1) month extension of time for filing a reply in connection with the present application, and the required fee of \$120.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark Konieczny (Reg. No. 47,715) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Application No. 10/621,329  
Amendment dated May 10, 2007  
Reply to Office Action of January 10, 2007

Docket No.: 0649-0965P

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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